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10/587,956	10/05/2007	Hyun-Ah Kang	HANOL-13037	2242
72960	7590	03/12/2010	EXAMINER	
Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562			RAGHU, GANAPATHIRAM	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application Status

In response to the Office Action mailed on 07/06/09, applicants' response and amendments received on 01/06/10 is acknowledged. Said amendment, amended claims 1- and 7-9, cancelled claim 10 and added a new claim 12. Thus, claims 1-9, 11 and new claim 12 are pending in the application and are now under consideration for examination.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn-Claim Rejections: 35 USC § 101

Previous rejection of claims 1-3 rejected under 35 U.S.C. 101, is being withdrawn due to amendments to claims.

Withdrawn-Claim Rejections: 35 USC § 112, second paragraph

Previous rejection of claim 8 rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to amendments to claim.

Withdrawn-Claim Rejections: 35 USC § 112, first paragraph

Previous rejection of claims 1-9 and 11 rejected under 35 U.S.C. 112, first paragraph for enablement and written description, is being withdrawn due to persuasive arguments and the availability of structural information (3-D structures) and structure-function co-relationship for mannosyltransferases (see enclosed RCSB protein databank structural hits for mannosyltransferases).

New-Claim Rejections: 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and claims 2-3 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which appellant regards as the invention. Claim1 recites the phrase “...derived from *Hansenula polymorpha*”. It is not clear to the examiner as to what the phrase “...derived from...” means in the context of the above claim, is this synonymous with “obtained from specific strain of *Hansenula polymorpha*” or does it include natural and man-made mutants thereof from any source, and perusal of the specification did not provide a definition for the phrase. Furthermore, literally while the term “derived” means to “to isolate from or obtain from a source”, the above term could also mean “to arrive by reasoning i. e., to deduce or infer” or also mean “to produce from another substance”. It is noted that while the term “derived” will encompass proteins naturally found in *Hansenula polymorpha*, the term in its broadest reasonable interpretation will also encompass any variant artificially created of a *Hansenula polymorpha* gene encoding the enzyme or a polypeptide (α -1,6-mannosyltransferase polypeptide) from any source. Since a protein activity is defined by its structure, if a man-made variant of a *Hansenula polymorpha* (α -1,6-mannosyltransferase polypeptide) has similar structure (i. e., α -1,6-mannosyltransferase polypeptide sequence) as that of a protein isolated from an organism which is not a *Hansenula polymorpha* gene encoding the enzyme or a gene encoding the enzyme or polypeptide, the term “derived...” would not allow one of skill in the art to differentiate between these proteins, especially when claims are given the broadest interpretation. Therefore, unless applicants’ have defined the term “derived...” as equivalent to “obtained from specific strain of *Hansenula polymorpha* gene encoding the enzyme”, the term “derived...” does not further limit the recited gene and encoding (α -1,6-mannosyltransferase).

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Clarification and correction is required. Examiner suggests amending the claim to recite "...obtained from...".

Claim 8 and claims 9 and 11 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is rejected for the phrase "...lacking α -1,6-mannosyltransferase activity", as the metes and bounds are not clear. It is not clear to the examiner as to any and all genes encoding any endogenous α -1,6-mannosyltransferase activity in said mutant is lacking for the following reason. The specification teaches the disruption of a specific endogenous gene of *Hansenula polymorpha* *Hpoch2Δ* mutant being disrupted by employing specific structures; primers disclosed in Table: 1, Example 2 of specification by homologous recombination method (α -1,6-mannosyltransferase encoded by the nucleic acid sequence of SEQ ID NO: 1 being disrupted). However, specification does not provide any guidance regarding disrupting and rendering any α -1,6-mannosyltransferase in said *Hansenula polymorpha* *Hpoch2Δ* mutant inactive. Clarification and correction is required.

Maintained-Claim Rejections: 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 4-6 and claims 8, 9, 11 and 12 depending therefrom are rejected under

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35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 4 recites a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession number KCTC 10583BP and claim 5 recites *Hansenula polymorpha Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP.

It is apparent that a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession number KCTC 10583BP and *Hansenula polymorpha Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP are required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC112, first paragraph, may be satisfied by a deposit of a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession number KCTC 10583BP and *Hansenula polymorpha Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP1. The specification does not disclose a repeatable method to obtain a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession number KCTC 10583BP and *Hansenula polymorpha Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP. It is noted that applicants have deposited the a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession

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number KCTC 10583BP and *Hansenula polymorpha* *Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP on 01/15/2007 with the Korean Collection for Type Cultures, #52, Oun-dong, Yusong-ku, Taejon 305-333, Korea (pages 11, 29 and 30 of specification), but there is no indication in the specification as to the public availability or the deposit was made under the terms of Budapest Treaty. A statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his/her signature and registration number, or someone empowered to make such a statement, stating that the invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. In order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make same, or by a statement by an attorney of record over his /her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;
- (c) the deposit will be maintained in public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and the deposit will be replaced if it should ever become inviable.

Examiner notes that the applicants' have not submitted any response or an affidavit indicating the availability of a recombinant vector comprising the nucleic acid molecule of SEQ ID NO: 1 deposited under accession number KCTC 10583BP and *Hansenula polymorpha* *Hpoch2Δ* mutant strain deposited under accession number KCTC 10584BP that are required to practice the claimed invention in their response dated 01/06/10.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

1) Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

2) Claims 4-6 and claims 8, 9, 11 and 12 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement/Biologic Deposit.

Allowable Subject Matter/Conclusion

None of the claims are allowable. Claims 1-9, 11 and 12 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

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Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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/Ganapathirama Raghu/
Patent Examiner
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